

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL
PRODUCTS R&D, INC., and
NORTON (WATERFORD) LTD.,

Plaintiffs,

v.

AUROBINDO PHARMA LTD.,
AUROBINDO PHARMA USA, INC.,
and AUROLIFE PHARMA LLC,

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. (“Teva”) and Norton (Waterford) Ltd. (“Norton”) (collectively, “Plaintiffs”), by their attorneys, for their Complaint, against Defendants Aurobindo Pharma Ltd. (“Aurobindo Ltd.”), Aurobindo Pharma USA, Inc. (“Aurobindo USA”), and Aurolife Pharma LLC (“Aurolife”) (collectively, “Aurobindo”), allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., which arises out of the submission by Aurobindo of Abbreviated New Drug Application No. 214418 (“Aurobindo’s ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of Plaintiffs’ Qvar® (beclomethasone dipropionate) products prior to the expiration of U.S. Patent Nos. 9,463,289 (the “’289 patent”), 9,808,587 (the “’587 patent”), 10,022,509 (the “’509 patent”), 10,022,510 (the “’510 patent”), 10,086,156 (the “’156 patent”), 10,561,808 (the “’808 patent”), and 10,695,512 (the “’512 patent”). Collectively, the ’289 patent,

'587 patent, '509 patent, '510 patent, '156 patent, '808 patent, and '512 patent are referred to herein as the "Patents-in-Suit."

PARTIES

Teva

2. Plaintiff Teva is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, Teva has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

3. Plaintiff Norton is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland. Norton trades, i.e., does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

Aurobindo

4. On information and belief, Defendant Aurobindo Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500 038, Telangana, Republic of India. On information and belief, Aurobindo Ltd. on its own and/or through its subsidiaries is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

5. On information and belief, Defendant Aurobindo USA is a company organized and existing under the laws of the State of Delaware with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. On information and belief, Aurobindo USA operates a distribution center at 6 Wheeling Road, Dayton, New Jersey 08810.

6. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd.

7. On information and belief, Defendant Aurolife is a corporation existing under the laws of the State of Delaware with its principal place of business at 2400 Route 130 North, Dayton, New Jersey 08810.

8. On information and belief, Aurolife is a wholly owned subsidiary of Aurobindo USA.

9. On information and belief, Aurolife is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Aurolife, acting in concert with Aurobindo Ltd. and Aurobindo USA, prepares and files ANDAs and similar regulatory submissions with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Aurolife, acting in concert with Aurobindo Ltd. and Aurobindo USA, files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (“Paragraph IV Certifications”) to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

10. On information and belief, Aurobindo Ltd., Aurobindo USA, and Aurolife acted in concert to prepare and submit Aurobindo’s ANDA to the FDA. On information and belief, Aurobindo Ltd. and Aurobindo USA encouraged Aurolife to prepare and submit Aurobindo’s ANDA to the FDA and knew that the filing of Aurobindo’s ANDA would infringe the Patents-in-Suit, including because Aurobindo Ltd. and Aurobindo USA knew that Aurobindo’s ANDA would

include a Paragraph IV Certification with respect to the Patents-in-Suit.

11. On information and belief, Aurobindo Ltd., Aurobindo USA, and Aurolife know and intend that upon approval of Aurobindo's ANDA, Aurobindo will manufacture and directly or indirectly market, sell, and distribute Aurobindo's Beclomethasone Dipropionate Aerosol, Metered; Inhalation (0.04 mg/inh and 0.08 mg/inh) Products ("Aurobindo's ANDA Products") throughout the United States, including in New Jersey. On information and belief, Aurobindo Ltd., Aurobindo USA, and Aurolife are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into New Jersey, and including with respect to Aurobindo's ANDA Products. On information and belief, Aurobindo Ltd., Aurobindo USA, and Aurolife participated in, assisted, and cooperated in the acts complained about herein.

12. On information and belief, following any FDA approval of Aurobindo's ANDA, Aurobindo Ltd., Aurobindo USA, and Aurolife will act in concert to distribute and sell Aurobindo's ANDA Product throughout the United States, including within New Jersey.

JURISDICTION AND VENUE

13. Plaintiffs incorporate each of the preceding paragraphs 1–12 as if fully set forth herein.

14. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Aurobindo Ltd., Aurobindo USA, and Aurolife.

16. This Court has personal jurisdiction over Aurobindo Ltd. because, among other things, Aurobindo Ltd., itself and through its subsidiaries Aurobindo USA and Aurolife, has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurobindo Pharma, Ltd., itself and through its subsidiaries Aurobindo USA and Aurolife, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey.

17. In addition, this Court has personal jurisdiction over Aurobindo Ltd. because, on information and belief, Aurobindo Ltd. controls Aurobindo USA and Aurolife, and therefore Aurobindo USA's and Aurolife's activities in New Jersey are attributable to Aurobindo Ltd.

18. This Court has personal jurisdiction over Aurobindo USA because, among other things, Aurobindo USA has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurobindo USA's principal place of business is in East Windsor, New Jersey. On information and belief, Aurobindo USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Entity Id. No. 0100921223. On information and belief, Aurobindo USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003120. On

information and belief, Aurobindo USA develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey. On information and belief, Aurobindo USA also prepares and/or aids in the preparation and submission of ANDAs to FDA.

19. This Court has personal jurisdiction over Aurolife because, among other things, Aurolife has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurolife develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey. On information and belief, Aurolife's principal place of business is in Dayton, New Jersey. On information and belief, Aurolife is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Entity Id. No. 0600322732. On information and belief, Aurolife is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003810. On information and belief, Aurolife also prepares and/or aids in the preparation and submission of ANDAs to FDA.

20. In addition, this Court has personal jurisdiction over Aurobindo Ltd., Aurobindo USA, and Aurolife because, among other things, on information and belief: (1) Aurobindo Ltd., Aurobindo USA, and Aurolife filed Aurobindo's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products in the United States, including in New Jersey; and

(2) upon approval of Aurobindo's ANDA, Aurobindo Ltd., Aurobindo USA, and Aurolife will market, distribute, offer for sale, sell, and/or import Aurobindo's ANDA Products in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Aurobindo's ANDA Products in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Aurobindo's ANDA, Aurobindo's ANDA Products will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

21. In addition, this Court has personal jurisdiction over Aurobindo Ltd., Aurobindo USA, and Aurolife because Aurobindo Ltd., Aurobindo USA, and Aurolife regularly (1) engage in patent litigation concerning Aurobindo's ANDA products in this District, (2) do not contest personal jurisdiction in this District, and (3) purposefully avail themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g., Merck Sharp & Dohme B.V. & Organon USA Inc. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 20-2576 (CCC)(MF) (D.N.J.) (Aurobindo Ltd., Aurobindo USA); *Celgene Corp. v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 20-315 (SDW)(LDW) (D.N.J.) (Aurobindo Ltd., Aurobindo USA, Aurolife); *Celgene Corp. v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 19-5799 (ES)(MAH) (D.N.J.) (Aurobindo Ltd., Aurobindo USA, Aurolife); *Celgene Corp. v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 19-0143 (ES)(MAH) (D.N.J.) (Aurobindo Ltd., Aurobindo USA, Aurolife); *Aurobindo Pharma Ltd., et al. v. AstraZeneca AB, et al.*, Civil Action No. 16-5079 (PGS)(TJB) (D.N.J.) (Aurobindo Ltd.); *Otsuka Pharm. Co., Ltd. v. Aurobindo Pharma Ltd.*,

et al., Civil Action No. 14-6890 (JBS)(KMW) (D.N.J.) (Aurobindo Ltd., Aurobindo USA, Aurolife).

22. For the above reasons, it would not be unfair or unreasonable for Aurobindo Ltd., Aurobindo USA, and Aurolife to litigate this action in this District, and the Court has personal jurisdiction over them here.

VENUE

23. Plaintiffs incorporate each of the proceeding paragraphs 1–22 as if fully set forth herein.

24. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Aurobindo Ltd., at least because, on information and belief, Aurobindo Ltd. is a foreign corporation that may be sued in any judicial district in which it is subject to the Court’s personal jurisdiction.

25. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Aurobindo USA, at least because, on information and belief, Aurobindo USA has a principal place of business in New Jersey, and because, on information and belief, Aurobindo USA has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in-Suit that will lead to foreseeable harm and injury to Teva by preparing or assisting in preparing Aurobindo’s ANDA in New Jersey and/or with the intention of seeking to market the Aurobindo ANDA Products nationwide, including within New Jersey.

26. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Aurolife, at least because, on information and belief, Aurolife has a principal place of business in New Jersey, and because, on information and believe, Aurolife has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the

Patents-in-Suit that will lead to foreseeable harm and injury to Teva by preparing or assisting in preparing Aurobindo's ANDA in New Jersey and/or with the intention of seeking to market the Aurobindo ANDA Products nationwide, including within New Jersey.

BACKGROUND

27. Teva is the holder of New Drug Application ("NDA") No. 20911 for Qvar® 40 mcg and Qvar® 80 mcg (beclomethasone dipropionate HFA 40 mcg and 80 mcg) Inhalation Aerosol. Teva's Qvar® inhalers are approved by FDA for maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older.

The '289 Patent

28. The '289 patent, entitled "Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof" (Exhibit A), duly and legally issued on October 11, 2016.

29. Norton is the owner and assignee of the '289 patent.

30. The '289 patent is listed in connection with Qvar® in the Orange Book.

31. Claim 1 of the '289 patent claims:

An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and

wherein the canister housing has a longitudinal axis X

which passes through the center of the central outlet port,

the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

The '587 Patent

32. The '587 patent, entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator" (Exhibit B), duly and legally issued on November 7, 2017.

33. Norton is the owner and assignee of the '587 patent.

34. The '587 patent is listed in connection with Qvar[®] in the Orange Book.

35. Claim 1 of the '587 patent claims:

An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and

wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main

body of the inhaler.

36. Claim 12 of the '587 patent claims:

An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,

wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and

wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.

37. Claim 13 of the '587 patent claims:

An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first

inner wall canister support formation extending inwardly from a main surface of the inner wall,

wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and

wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

The '509 Patent

38. The '509 patent, entitled "Dose Counter for Inhaler Having a Bore and Shaft Arrangement" (Exhibit C), duly and legally issued on July 17, 2018.

39. Norton is the owner and assignee of the '509 patent.

40. The '509 patent is listed in connection with Qvar[®] in the Orange Book.

41. Claim 1 of the '509 Patent claims:

A dose counter for an inhaler, the dose counter having a display tape arranged to be incrementally driven from a tape stock bobbin onto an incremental tape take-up drive shaft, the bobbin having an internal bore supported by and for rotation about a support shaft, at least one of the bore and the support shaft having a radially extending protrusion having a leading portion edge, a trailing portion edge, wherein at least one of the leading portion edge and the trailing portion edge are tapered, and a friction edge between the leading portion edge and the trailing portion edge, wherein the friction edge is substantially parallel to a longitudinal axis of the support shaft and the leading portion edge and trailing portion edge are not parallel to the longitudinal axis of the support shaft, and the friction edge is resiliently biased into frictional engagement with the other of the bore and support shaft with longitudinally extending mutual frictional interaction and wherein the friction edge extends further in a longitudinal direction than the protrusion extends radially.

The '510 Patent

42. The '510 patent, entitled "Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof" (Exhibit D), duly and legally issued on July 17, 2018.

43. Norton is the owner and assignee of the '510 patent.
44. The '510 patent is listed in connection with Qvar[®] in the Orange Book.
45. Claim 1 of the '510 patent claims:

An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:

a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure, a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, and priming indicia located on the main elongate tape structure, the priming indicia being located between the dosing indicia and a first end of the main elongate tape structure and visible in the dose counter viewing window before priming before first use, and

wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

46. Claim 10 of the '510 patent claims:

An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:

a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure, and a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, wherein the tape size marker is positioned between a first end of the main elongate tape structure and the tape positioning indicia,

wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the tape is around both the stock bobbin and tape reel shaft and a portion of the main elongate tape structure between the tape positioning indicia and the dosing indicia is visible in the dose counter viewing window before priming before first use.

47. Claim 20 of the '510 patent claims:

An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:

a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure so as to be visible in the dose counter viewing window before priming before first use, and priming indicia located on the main elongate tape structure, the priming indicia being located between the tape positioning indicia and the dosing indicia,

wherein a first end of the main elongate tape structure is attached to a stock bobbin and a second end of the main elongate tape structure is fixed to a tape reel shaft, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

The '156 Patent

48. The '156 patent, entitled "Dose Counter for Inhaler and Method of Counting Doses" (Exhibit E), duly and legally issued on October 2, 2018.

49. Norton is the owner and assignee of the '156 patent.

50. The '156 patent is listed in connection with Qvar[®] in the Orange Book.

51. Claim 1 of the '156 patent claims:

A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for

movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

a ratchet wheel having a plurality of circumferentially spaced teeth,

an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,

a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth, and

a dosage indicator associated with the count pawl,

wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth,

wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count,

wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

The '808 Patent

52. The '808 patent, entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator" (Exhibit F), duly and legally issued on February 18, 2020.

53. Norton is the owner and assignee of the '808 patent.

54. The '808 patent is listed in connection with Qvar[®] in the Orange Book.

55. Claim 1 of the '808 patent claims:

A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

The '512 Patent

56. The '512 patent, entitled "Dose Counters for Inhaler Having an Anti-Reverse Rotation Actuator" (Exhibit G), duly and legally issued on June 30, 2020.

57. Norton is the owner and assignee of the '512 patent.

58. The '512 patent is listed in connection with Qvar[®] in the Orange Book.

59. Claim 1 of the '512 patent claims:

An inhaler for inhaling medicament, the inhaler having:

A body for retaining a medicament canister; and

a dose counter, the dose counter having a moveable actuator and a chassis mounted on the body;

wherein one of the body and the chassis includes a plurality of apertures for receiving one or more pins on the other of the body and the chassis,

wherein either the pins or the apertures on the chassis are positioned on different sides of the chassis for stabilizing the chassis on the body, and

wherein the chassis comprises at least one of a pin or aperture heat staked to a respective aperture or pin of the body to mount the chassis to the body.

INFRINGEMENT BY AUROBINDO

60. By letter dated September 7, 2020 (“Aurobindo’s Notice Letter”), Aurobindo notified Teva that it had filed a Paragraph IV Certification with respect to the Patents-in-Suit and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo’s ANDA Products prior to the expiration of the Patents-in-Suit. On information and belief, Aurobindo’s ANDA contains a Paragraph IV Certification asserting that Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of Aurobindo’s ANDA Products, or alternatively, that the Patents-in-Suit are invalid.

61. The purpose of Aurobindo’s submission of Aurobindo’s ANDA was to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo’s ANDA Products prior to the expiration of the Patents-in-Suit.

62. In Aurobindo’s Notice Letter, Aurobindo stated that the subject of Aurobindo’s ANDA is “beclomethasone dipropionate aerosol, metered; inhalation having the following strengths, (0.04 mg/inh and 0.08 mg/inh).”

63. In Aurobindo’s Notice Letter, Aurobindo stated that the active ingredient of Aurobindo’s ANDA Products is beclomethasone dipropionate.

64. In Aurobindo’s Notice Letter, Aurobindo stated that the proposed dosage strengths of Aurobindo’s ANDA Products are 0.04 mg/inh and 0.08 mg/inh.

65. In Aurobindo’s Notice Letter, Aurobindo stated that the dosage form of Aurobindo’s ANDA Products is a metered aerosol inhalation.

66. Aurobindo's Notice Letter purported to provide Teva with an Offer of Confidential Access ("OCA") to portions of Aurobindo's ANDA. That offer, however, was both insufficient and subject to various unreasonably restrictive conditions.

67. By correspondence and phone, Teva's counsel and Aurobindo's counsel discussed the terms of Aurobindo's OCA.

68. On September 22, 2020, Teva's counsel sent Aurobindo's counsel a letter identifying various unreasonably restrictive terms in Aurobindo's OCA, including but not limited to restrictions on the conduct of Teva's outside counsel in future post-grant and FDA proceedings, prohibitions on providing information to outside consultants, choice of law, and limitations on the scope of documents Aurobindo would provide to Teva.

69. On October 6, 2020, Aurobindo's counsel sent Teva's counsel a revised OCA. That offer addressed some of Teva's concerns but remained unreasonably restrictive, including with respect to prohibitions on the use of Aurobindo's information, among other concerns. On the same day, Teva's and Aurobindo's counsel met and conferred by phone to discuss Aurobindo's revised OCA and the parties' disagreements. Aurobindo refused to represent that it would, in a timely fashion, provide the documents and materials requested by Teva necessary to evaluate Aurobindo's ANDA Products for infringement.

70. On October 14, 2020, Teva's counsel sent Aurobindo's counsel a second letter, reiterating Teva's concerns regarding the restrictions in Aurobindo's OCA, including the need for specific materials to evaluate infringement.

71. Teva's counsel has not received a response to its October 14, 2020 letter.

72. Aurobindo's Notice Letter appends a document titled "Detailed Statement" asserting that the commercial manufacture, use, or sale of Aurobindo's ANDA Products will not

infringe any of the Patents-in-Suit. However, Aurobindo's Notice Letter and "Detailed Statement" do not provide information regarding Aurobindo's ANDA Products sufficient to evaluate Aurobindo's assertions of non-infringement.

73. This action is being commenced before the expiration of forty-five days from the date of the receipt of Aurobindo's Notice Letter.

**COUNT I – INFRINGEMENT BY AUROBINDO
OF THE '289 PATENT UNDER 35 U.S.C. § 271(e)(2)**

74. Plaintiffs incorporate each of the preceding paragraphs 1–73 as if fully set forth herein.

75. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products prior to the expiration of the '289 patent was an act of infringement of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

76. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '289 patent, recited above, either literally or under the doctrine of equivalents.

77. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

78. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '289 patent, recited above.

79. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '289 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

80. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '289 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '289 patent after approval of Aurobindo's ANDA.

81. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '289 patent, active inducement of infringement of the '289 patent, and contribution to the infringement by others of the '289 patent.

82. On information and belief, Aurobindo has acted with full knowledge of the '289 patent and without a reasonable basis for believing that it would not be liable for infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent.

83. Unless Aurobindo is enjoined from infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT II – INFRINGEMENT BY AUROBINDO
OF THE '587 PATENT UNDER 35 U.S.C. § 271(e)(2)**

84. Plaintiffs incorporate each of the preceding paragraphs 1–83 as if fully set forth herein.

85. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or

importation of Aurobindo's ANDA Products prior to the expiration of the '587 patent was an act of infringement of the '587 patent under 35 U.S.C. § 271(e)(2)(A).

86. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claims 1, 12, and/or 13 of the '587 patent, recited above, either literally or under the doctrine of equivalents.

87. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

88. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claims 1, 12, and/or 13 of the '587 patent, recited above.

89. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '587 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

90. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '587 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '587 patent after approval of Aurobindo's ANDA.

91. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '587 patent, active inducement of infringement of the '587 patent, and contribution to the infringement by others of the '587 patent.

92. On information and belief, Aurobindo has acted with full knowledge of the '587 patent and without a reasonable basis for believing that it would not be liable for infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent.

93. Unless Aurobindo is enjoined from infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT III – INFRINGEMENT BY AUROBINDO
OF THE '509 PATENT UNDER 35 U.S.C. § 271(e)(2)**

94. Plaintiffs incorporate each of the preceding paragraphs 1–93 as if fully set forth herein.

95. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products prior to the expiration of the '509 patent was an act of infringement of the '509 patent under 35 U.S.C. § 271(e)(2)(A).

96. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '509 patent, recited above, either literally or under the doctrine of equivalents.

97. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

98. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '509 patent, recited above.

99. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '509 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

100. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '509 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '509 patent after approval of Aurobindo's ANDA.

101. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '509 patent, active inducement of infringement of the '509 patent, and contribution to the infringement by others of the '509 patent.

102. On information and belief, Aurobindo has acted with full knowledge of the '509 patent and without a reasonable basis for believing that it would not be liable for infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent.

103. Unless Aurobindo is enjoined from infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT IV – INFRINGEMENT BY AUROBINDO
OF THE '510 PATENT UNDER 35 U.S.C. § 271(e)(2)**

104. Plaintiffs incorporate each of the preceding paragraphs 1–103 as if fully set forth herein.

105. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or

importation of Aurobindo's ANDA Products prior to the expiration of the '510 patent was an act of infringement of the '510 patent under 35 U.S.C. § 271(e)(2)(A).

106. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above, either literally or under the doctrine of equivalents.

107. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

108. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above.

109. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '510 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

110. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '510 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '510 patent after approval of Aurobindo's ANDA.

111. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '510 patent, active inducement of infringement of the '510 patent, and contribution to the infringement by others of the '510 patent.

112. On information and belief, Aurobindo has acted with full knowledge of the '510 patent and without a reasonable basis for believing that it would not be liable for infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent.

113. Unless Aurobindo is enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT V – INFRINGEMENT BY AUROBINDO
OF THE '156 PATENT UNDER 35 U.S.C. § 271(e)(2)**

114. Plaintiffs incorporate each of the preceding paragraphs 1–113 as if fully set forth herein.

115. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products prior to the expiration of the '156 patent was an act of infringement of the '156 patent under 35 U.S.C. § 271(e)(2)(A).

116. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '156 patent, recited above, either literally or under the doctrine of equivalents.

117. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

118. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '156 patent, recited above.

119. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '156 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

120. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '156 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '156 patent after approval of Aurobindo's ANDA.

121. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '156 patent, active inducement of infringement of the '156 patent, and contribution to the infringement by others of the '156 patent.

122. On information and belief, Aurobindo has acted with full knowledge of the '156 patent and without a reasonable basis for believing that it would not be liable for infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent.

123. Unless Aurobindo is enjoined from infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VI – INFRINGEMENT BY AUROBINDO
OF THE '808 PATENT UNDER 35 U.S.C. § 271(e)(2)**

124. Plaintiffs incorporate each of the preceding paragraphs 1–123 as if fully set forth herein.

125. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or

importation of Aurobindo's ANDA Products prior to the expiration of the '808 patent was an act of infringement of the '808 patent under 35 U.S.C. § 271(e)(2)(A).

126. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '808 patent, recited above, either literally or under the doctrine of equivalents.

127. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

128. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '808 patent, recited above.

129. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '808 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

130. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '808 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '808 patent after approval of Aurobindo's ANDA.

131. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

132. On information and belief, Aurobindo has acted with full knowledge of the '808 patent and without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

133. Unless Aurobindo is enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VII – INFRINGEMENT BY AUROBINDO
OF THE '512 PATENT UNDER 35 U.S.C. § 271(e)(2)**

134. Plaintiffs incorporate each of the preceding paragraphs 1–133 as if fully set forth herein.

135. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products prior to the expiration of the '512 patent was an act of infringement of the '512 patent under 35 U.S.C. § 271(e)(2)(A).

136. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '512 patent, recited above, either literally or under the doctrine of equivalents.

137. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

138. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '512 patent, recited above.

139. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '512 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

140. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '512 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '512 patent after approval of Aurobindo's ANDA.

141. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '512 patent, active inducement of infringement of the '512 patent, and contribution to the infringement by others of the '512 patent.

142. On information and belief, Aurobindo has acted with full knowledge of the '512 patent and without a reasonable basis for believing that it would not be liable for infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent.

143. Unless Aurobindo is enjoined from infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '289 PATENT**

144. Plaintiffs incorporate each of the preceding paragraphs 1–143 as if fully set forth herein.

145. Aurobindo has knowledge of the '289 patent.

146. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '289 patent, recited above, either literally or under the doctrine of equivalents.

147. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

148. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '289 patent, recited above.

149. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '289 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

150. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '289 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '289 patent after approval of Aurobindo's ANDA.

151. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '289 patent, active inducement of infringement of the '289 patent, and contribution to the infringement by others of the '289 patent.

152. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent.

153. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products with their proposed labeling according to Aurobindo's ANDA will infringe at least claim 1 of the '289 patent, recited above, and whether those claims of the '289 patent are valid.

154. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '289 patent and that the claims of the '289 patent are valid.

155. Aurobindo should be enjoined from infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT IX – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '587 PATENT**

156. Plaintiffs incorporate each of the preceding paragraphs 1–155 as if fully set forth herein.

157. Aurobindo has knowledge of the '587 patent.

158. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claims 1, 12, and/or 13 of the '587 patent, recited above, either literally or under the doctrine of equivalents.

159. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

160. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claims 1, 12, and/or 13 of the '587 patent, recited above.

161. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '587 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

162. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '587 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '587 patent after approval of Aurobindo's ANDA.

163. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '587 patent, active inducement of infringement of the '587 patent, and contribution to the infringement by others of the '587 patent.

164. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent.

165. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products with their proposed

labeling according to Aurobindo's ANDA will infringe at least claims 1, 12, and/or 13 of the '587 patent, recited above, and whether those claims of the '587 patent are valid.

166. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '587 patent and that the claims of the '587 patent are valid.

167. Aurobindo should be enjoined from infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT X – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '509 PATENT**

168. Plaintiffs incorporate each of the preceding paragraphs 1–167 as if fully set forth herein.

169. Aurobindo has knowledge of the '509 patent.

170. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '509 patent, recited above, either literally or under the doctrine of equivalents.

171. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

172. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '509 patent, recited above.

173. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '509 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

174. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '509 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '509 patent after approval of Aurobindo's ANDA.

175. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '509 patent, active inducement of infringement of the '509 patent, and contribution to the infringement by others of the '509 patent.

176. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent.

177. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products with their proposed labeling according to Aurobindo's ANDA will infringe at least claim 1 of the '509 patent, recited above, and whether those claims of the '509 patent are valid.

178. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '509 patent and that the claims of the '509 patent are valid.

179. Aurobindo should be enjoined from infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XI – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '510 PATENT**

180. Plaintiffs incorporate each of the preceding paragraphs 1–179 as if fully set forth herein.

181. Aurobindo has knowledge of the '510 patent.

182. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above, either literally or under the doctrine of equivalents.

183. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

184. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above.

185. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '510 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

186. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '510 patent and

that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '510 patent after approval of Aurobindo's ANDA.

187. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '510 patent, active inducement of infringement of the '510 patent, and contribution to the infringement by others of the '510 patent.

188. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent.

189. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products with their proposed labeling according to Aurobindo's ANDA will infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above, and whether those claims of the '510 patent are valid.

190. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '510 patent and that the claims of the '510 patent are valid.

191. Aurobindo should be enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XII – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '156 PATENT**

192. Plaintiffs incorporate each of the preceding paragraphs 1–191 as if fully set forth herein.

193. Aurobindo has knowledge of the '156 patent.

194. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe of at least claim 1 of the '156 patent, recited above, either literally or under the doctrine of equivalents.

195. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

196. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '156 patent, recited above.

197. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '156 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

198. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '156 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '156 patent after approval of Aurobindo's ANDA.

199. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '156 patent, active inducement of infringement of the '156 patent, and contribution to the infringement by others of the '156 patent.

200. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent.

201. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products with their proposed labeling according to Aurobindo's ANDA will infringe at least claim 1 of the '156 patent, recited above, and whether one or those claims of the '156 patent are valid.

202. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '156 patent and that the claims of the '156 patent are valid.

203. Aurobindo should be enjoined from infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XIII – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '808 PATENT**

204. Plaintiffs incorporate each of the preceding paragraphs 1–203 as if fully set forth herein.

205. Aurobindo has knowledge of the '808 patent.

206. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '808 patent, recited above, either literally or under the doctrine of equivalents.

207. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

208. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '808 patent, recited above.

209. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '808 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

210. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '808 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '808 patent after approval of Aurobindo's ANDA.

211. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

212. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

213. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products with their proposed labeling according to Aurobindo's ANDA will infringe at least claim 1 of the '808 patent, recited above, and whether those claims of the '808 patent are valid.

214. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '808 patent and that the claims of the '808 patent are valid.

215. Aurobindo should be enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XIV – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '512 PATENT**

216. Plaintiffs incorporate each of the preceding paragraphs 1–215 as if fully set forth herein.

217. Aurobindo has knowledge of the '512 patent.

218. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '512 patent, recited above, either literally or under the doctrine of equivalents.

219. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

220. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '512 patent, recited above.

221. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '512 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

222. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '512 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '512 patent after approval of Aurobindo's ANDA.

223. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '512 patent, active inducement of infringement of the '512 patent, and contribution to the infringement by others of the '512 patent.

224. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent.

225. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products with their proposed labeling according to Aurobindo's ANDA will infringe at least claim 1 of the '512 patent, recited above, and whether those claims of the '512 patent are valid.

226. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '512 patent and that the claims of the '512 patent are valid.

227. Aurobindo should be enjoined from infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

- (a) A judgment that Aurobindo has infringed, will infringe, and will induce and contribute to infringement of each of the Patents-in-Suit;
- (b) A judgment that the Patents-in-Suit are valid and enforceable;
- (c) A judgment pursuant to, among other things, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Aurobindo to make, use, offer for sale, sell, market, distribute, or import Aurobindo's ANDA Products, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;
- (d) A preliminary and permanent injunction pursuant to, among other things, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Aurobindo, its officers,

agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Aurobindo's ANDA Products, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

- (e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Aurobindo's ANDA Products, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;
- (f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Aurobindo engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Aurobindo's ANDA Products, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s)

and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

- (g) A declaration that this case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
- (h) An award of Plaintiffs' costs and expenses in this action; and
- (i) Such further and other relief as this Court may deem just and proper.

Dated: October 22, 2020

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

OF COUNSEL:

David I. Berl

Elise M. Baumgarten

Kathryn S. Kayali

Ben Picozzi

Ricardo Leyva

WILLIAMS & CONNOLLY LLP

725 Twelfth Street, N.W.

Washington, DC 20005

(202) 434-5000

Liza M. Walsh

Katelyn O'Reilly

William T. Walsh, Jr.

100 Mulberry Street, 15th Floor

Newark, New Jersey 07102

(973) 757-1100

*Attorneys for Plaintiffs Teva Branded
Pharmaceutical Products R&D, Inc. and
Norton (Waterford) Ltd.*

Local Rule 11.2 Certification

We hereby certify that, to the best of our knowledge, the matter in controversy is related to the following action:

- *Teva Branded Pharm. Prods. R&D, Inc. v. Cipla Ltd.*, Civil Action No. 20-10172 (MCA)(MAH).

Dated: October 22, 2020

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

OF COUNSEL:

David I. Berl
Elise M. Baumgarten
Kathryn S. Kayali
Ben Picozzi
Ricardo Leyva
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000

Liza M. Walsh
Katelyn O'Reilly
William T. Walsh, Jr.
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

*Attorneys for Plaintiffs Teva Branded
Pharmaceutical Products R&D, Inc. and
Norton (Waterford) Ltd.*

Local Rule 201.1 Certification

We hereby certify that the above captioned matter is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief.

Dated: October 22, 2020

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

OF COUNSEL:

David I. Berl

Elise M. Baumgarten

Kathryn S. Kayali

Ben Picozzi

Ricardo Leyva

WILLIAMS & CONNOLLY LLP

725 Twelfth Street, N.W.

Washington, DC 20005

(202) 434-5000

Liza M. Walsh

Katelyn O'Reilly

William T. Walsh, Jr.

100 Mulberry Street, 15th Floor

Newark, New Jersey 07102

(973) 757-1100

*Attorneys for Plaintiffs Teva Branded
Pharmaceutical Products R&D, Inc. and
Norton (Waterford) Ltd.*